HFA-305, Div. of Dockets Mgt.

Date of Approval: JUN 2 3 2005

FREEDOM OF INFORMATION SUMMARY

SUPPLEMENTAL NEW ANIMAL DRUG APPLICATION

NADA 141-095

DECTOMAX (doramectin) Pour-On

"To add persistent effect periods for *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment"

Sponsored by:
Pfizer, Inc

2005-141-095

FOIS 2

1. GENERAL INFORMATION

a.	File Number:	NADA 141-095
b.	Sponsor:	Pfizer, Inc 235 East 42d St. New York, NY 10017 Drug Labeler Code: 000069
c.	Established Name:	Doramectin
d.	Proprietary Name:	DECTOMAX Pour-On
e.	Dosage Form:	Solution
f.	How Supplied:	250 mL, 1 liter, 2.5 liter, and 5 liter containers
g.	How Dispensed:	Over-the-Counter (OTC)
h.	Amount of Active Ingredients:	5 mg doramectin/mL
i.	Route of Administration:	Topical
j.	Species/Class:	Beef cattle & Dairy cattle less than 20 months
k.	Recommended Dosage:	Administer 500 mcg doramectin/kg (227 mcg/lb) of body weight. Each mL contains 5 mg of doramectin, sufficient to treat 22 lb (10 kg) of body weight.
l.	Pharmacological Category:	Antiparasitic

m. Indications: For the treatment and control of the following in cattle.

Gastrointestinal Roundworms	
Ostertagia ostertagi	Adults and L_4, including inhibited larvae
Ostertagia lyrata	Adults
Haemonchus placei	Adults and L_4
Trichostrongylus axei	Adults and L_4
T. colubriformis	Adults and L_4
Cooperia oncophora[1]	Adults and L_4
C. pectinata	Adults
C. punctata	Adults and L_4
C. surnabada	Adults
Bunostomum phlebotomum	Adults
Oesophagostomum radiatum	Adults and L_4
Trichuris spp.	Adults

[1]Efficacy below 90% was observed against adult *Cooperia oncophora* in some clinical studies

Lungworms	
Dictyocaulus viviparus	Adults and L_4
Eyeworms	
Thelazia gulosa	Adults
Thelazia skrjabini	Adults
Grubs	
Hypoderma bovis	
H. lineatum	
Sucking Lice	
Haematopinus eurysternus	
Linognathus vituli	
Solenopotes capillatus	
Biting Lice	
Bovicola (Damalinia) bovis	
Mange Mites	
Chorioptes bovis	
Sarcoptes scabiei	
Horn Flies	
Haematobia irritans	

DECTOMAX Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora, Dictyocaulus viviparus, Ostertagia ostertagi,* and *Oesophagostomum radiatum* for 28 days; and *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment.

n. Effect of Supplement: This supplement allows the following additional persistent effect indications. DECTOMAX Pour-On solution has been proved to effectively control infestations and to protect cattle from reinfestation with *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment.

2. *EFFECTIVENESS*

a. Dose Characterization

Effectiveness studies were presented in the original NADA 141-095 FOI Summary approval dated September 16, 1997, establishing the recommended effective dose of DECTOMAX Pour-On for the treatment and control of internal and external parasites.

b. Substantial Evidence

Two dose confirmation studies, conducted under the same protocol, evaluated the persistent effect of DECTOMAX Pour-On, administered topically at a dose of 500 mcg/kg against infestations of *Linognathus vituli* and *Bovicola (Damalinia) bovis*.

In each study, twenty-four (24) adequately infested mixed-sex beef calves (principals) having at least 5 *B. bovis* and 10 *L. vituli* were randomly and equally assigned to either the DECTOMAX Pour-On vehicle group or the DECTOMAX Pour-On group. From Day -1 to Day 35, the calves were kept in pens by treatment group. From Day 35 to Day 182, all calves were commingled in one pen. On Day 0, DECTOMAX Pour-On or vehicle was applied to the principal calves as indicated by treatment group. Lice counts of 9 predefined body regions were performed on these calves on Day -1 and Day 35. The pre-treatment lice infestations were cleared from the calves treated with DECTOMAX Pour-On by Day 35. To determine the persistent effect of DECTOMAX Pour-On, two seeder calves that were adequately infested with *B. bovis* and *L. vituli* were introduced to the pen where the principal calves were housed on Days 35, 63, 91, 119, and 147. The seeder calves remained in the pen for the duration of the study. Two louse-free sentinel calves were introduced to the pen on Days 35, 56, 77, 98, 119, 140, and 161 to confirm that natural contact transmission of lice was occurring. The sentinel calves were removed from the pen 28 days after entry. Lice counts were done every 7 days from Day 35 through Day 182 on the principal, seeder, and sentinel calves during the period they were in the pen.

For each study, percent efficacy was determined by comparing the geometric mean lice counts of the treated group with those of an untreated control group for each species present in at least six adequately infested control animals at each count day using Abbot's formula. A general linear repeated-measures mixed model was used to analyze log transformed lice counts. The significance for the louse count comparisons was set at $P<0.05$. The persistent effect period was determined at each count day when there was an adequate level of infestation in at least 6 control animals, a statistically significant difference between treated and control animals at $P<0.05$, and 95% efficacy using geometric means for each genus species of parasite. Using these criteria the two studies supported a persistent effect against *Linognathus vituli* for 42 days and *Bovicola (Damalinia) bovis* for 77 days after treatment.

The two studies are summarized below.

B.1 Dose Confirmation Study 2039B-60-99-119

1) Investigator: John E. Lloyd, Ph.D.
Jim W. Waggoner, Ph.D., P.A.S.
University of Wyoming
Laramie, Wyoming

2) General Design:

a. Purpose: To evaluate the persistent efficacy of DECTOMAX Pour-On administered at a dose of 500 mcg/kg body weight to *Bovicola (Damalinia) bovis* and *Linognathus vituli* infested cattle that are housed with untreated calves with *Bovicola (Damalinia) bovis* and *Linognathus vituli* infestations.

b. Animals: Male castrate and female beef cross-bred calves 4 to 10 months old were used. There were twenty-four (24) principal animals weighing 165 to 246 kg at the start of the study (twelve per treatment group). There were ten (10) infested seeder calves weighing 183 to 261 kg and fourteen (14) non-treated non-infested sentinel calves weighing 175 to 231 kg.

c. Infestation: The principal calves were naturally infested with *Bovicola (Damalinia) bovis* and *Linognathus vituli* at the start of the study. Additional louse exposure came by natural transfer from seeder calves introduced into the pen periodically for the duration of the study.

d. Controls: There were twelve (12) animals in the negative control group that received vehicle.

e. Treatment Regimen: The principal calves were given a single administration of 1 mL/10 kg body weight of vehicle or doramectin (500 mcg doramectin/kg body weight) on Day 0.

f. Study Duration: 182 days

g. Primary Variable: The density of louse populations was assessed by summing the lice counts within pre-defined areas of examination on 9 body regions on Days -1, 35, 42, 49, 56, 70, 77, 84, 91, 98, 105, 112, 119, 126, 133, 140, 147, 154, 161, 168, 175, and 182.

3) Results: There was an adequate level of infestation of *Bovicola (Damalinia) bovis* in the 12 vehicle control calves throughout the study. For *Linognathus vituli*, the infestation was adequate through Day 42. On Day 35 the treatment was 100% effective against *Bovicola (Damalinia) bovis* and *Linognathus vituli*. The period of persistent effect demonstrated against *Bovicola (Damalinia) bovis* was 98 days and against *Linognathus vituli* was 42 days. The results are summarized in Table 2.1 for *Bovicola (Damalinia) bovis* and Table 2.2 for *Linognathus vituli*.

Table 2.1 Study 2039B-60-99-119 – Persistent Efficacy (based on Geometric Means) of DECTOMAX Pour-On Against *Bovicola (Damalinia) bovis*

Day of Study	Geometric Mean Lice Counts: Vehicle Control	Geometric Mean Lice Counts: DECTOMAX Pour-On	P-value[a]	% Efficacy[b]
-1	13.3	12.4	-	-
35	27.3	0	-	100.0
42	30.8	0.7	0.0001	97.7
49	30.4	0.1	0.0001	99.8
56	33.3	0.3	0.0001	99.2
63	48.1	0.7	0.0001	98.6
70	43.2	0.7	0.0001	98.4
77	36.3	0.7	0.0001	98.2
84	36.1	0.2	0.0001	99.6
91	34.3	0.2	0.0001	99.3
98	39.8	1.2	0.0001	97.1
105	50.2	2.6	0.0001	94.8
112	47.4	2.8	0.0001	94.1
119	74.9	3.3	0.0001	95.6
126	58.4	6.8	0.0001	88.4
133	44.7	8.1	0.0001	81.8
140	44.3	9.0	0.0008	79.8
147	45.6	13.3	0.0072	70.7
154	47.4	32.6	0.2991	31.4
161	49.8	44.7	0.7689	10.1
168	39.5	49.8	0.6148	-
175	27.3	45.6	0.1689	-
182	28.6	44.5	0.1733	-

[a] P-value: Statistical significance at alpha = 0.05

[b] % efficacy = $\frac{\text{Mean no. of lice vehicle-treated group} - \text{Mean no. lice doramectin-treated group}}{\text{Mean no. of lice vehicle-treated group}} \times 100$

Table 2.2 Study 2039B-60-99-119 – Persistent Efficacy (based on Geometric Means) of DECTOMAX Pour-On Against *Linognathus vituli*

Day of Study	Geometric Mean Lice Counts: Vehicle Control	Geometric Mean Lice Counts: DECTOMAX Pour-On	P-value[a]	% Efficacy[b]
-1	34.5	33.9	-	-
35	14.5	0.0	-	100.0
42	10.6	0.0	0.0001	100.0
49	3.8	0.1	0.0001	98.5
56	2.0	0.0	0.0018	100.0
63	1.6	0.0	0.0054	100.0
70	1.3	0.0	0.0166	100.0
77	1.5	0.0	0.0093	100.0
84	1.9	0.0	0.0024	100.0
91	2.3	0.0	0.0006	100.0
98	3.3	0.1	0.0001	98.2
105	4.5	0.0	0.0001	100.0
112	5	0.1	0.0001	97.6
119	3.8	0.1	0.0001	96.7
126	2.3	0.1	0.0021	94.6
133	4.4	0.2	0.0001	96.3
140	2.4	0.2	0.0019	93.3
147	4.5	0.5	0.0002	88.6
154	3.3	0.6	0.0048	81.5
161	4.8	1.3	0.0069	73.5
168	3.3	1.3	0.0735	60.3
175	2.2	2.6	0.7240	-
182	2.2	3.1	0.4724	-

[a] P-value: Statistical significance at alpha = 0.05

[b] % efficacy = $\frac{\text{Mean no. of lice vehicle-treated group – Mean no. lice doramectin-treated group}}{\text{Mean no. of lice vehicle-treated group}} \times 100$

4) Adverse Events: No treatment related health problems were observed during this study.

B.2 Dose Confirmation Study 2039B-60-99-120

1) Investigator: Larry L. Smith, D.V.M.
Research and Development, Inc.
108 Davis Street
Lodi, Wisconsin

2) General Design:

a. Purpose: To evaluate the persistent efficacy of DECTOMAX Pour-On administered at a dose of 500 mcg/kg body weight to *Bovicola (Damalinia) bovis* and *Linognathus vituli* infested cattle that are housed with untreated calves with *Bovicola (Damalinia) bovis* and *Linognathus vituli* infestations.

b. Animals: Male castrate and female beef cross-bred calves 4 to 8 months old were used. There were twenty-four (24) principal animals weighing 119 to 197 kg at the start of the study (twelve per treatment group). There were ten (10) infested seeder calves weighing 129 to 321 kg and fourteen (14) non-treated non-infested sentinel calves weighing 217 to 352 kg.

c. Infestation: The principal calves were naturally infested with *Bovicola (Damalinia) bovis* and *Linognathus vituli* at the start of the study. Additional louse exposure came by natural transfer from seeder calves introduced into the pen periodically for the duration of the study.

d. Controls: There were twelve (12) animals in the negative control group that received vehicle.

e. Treatment Regimen: The principal calves were given a single administration of 1 mL/10 kg body weight of vehicle or doramectin (500 mcg doramectin/kg body weight) on Day 0.

f. Study Duration: 182 days

g. Primary Variable: The density of louse populations was assessed by summing the lice counts within pre-defined areas of examination on 9 body regions on Days -1, 35, 42, 49, 56, 70, 77, 84, 91, 98, 105, 112, 119, 126, 133, 140, 147, 154, 161, 168, 175, and 182.

3) Results: There was an adequate level of infestation of *Bovicola (Damalinia) bovis* in the 12 vehicle control calves throughout the study. For *Linognathus vituli*, the infestation was adequate through Day 154. On Day 35 the treatment was 100% effective against *Bovicola (Damalinia) bovis* and *Linognathus vituli*. The period of persistent effect demonstrated against *Bovicola (Damalinia) bovis* was 77 days and against *Linognathus vituli* was 105 days. The results are summarized in Table 2.3 for *Bovicola (Damalinia) bovis* and Table 2.4 for *Linognathus vituli*.

Table 2.3 Study 2039B-60-99-120 – Persistent Efficacy (based on Geometric Means) of DECTOMAX Pour-On Against *Bovicola (Damalinia) bovis*

Day of Study	Geometric Mean Lice Counts: Vehicle Control	Geometric Mean Lice Counts: DECTOMAX Pour-On	P-value[a]	% Efficacy[b]
-1	34.7	55.6	-	-
35	210.3	0.0	-	100.0
42	182.3	1.0	0.0001	99.5
49	249.4	1.1	0.0001	99.6
56	230.7	2.2	0.0001	99.0
63	219.3	5.1	0.0001	97.7
70	227.1	6.4	0.0001	97.2
77	202.4	5.5	0.0001	97.3
84	214.0	13.9	0.0001	93.5
91	189.3	19.7	0.0001	89.6
98	197.3	41.6	0.0001	78.9
105	169.1	84.2	0.0302	50.2
112	155.7	115.4	0.4068	25.9
119	142.9	167.7	0.6253	-
126	101.1	151.9	0.1936	-
133	123.6	201.8	0.0791	-
140	82.1	147.3	0.0502	-
147	70.1	122.0	0.0819	-
154	57.1	87.0	0.2821	-
161	28.3	82.3	0.0448	-
168	43.3	63.1	0.3541	-
175	25.7	41.4	0.3295	-
182	20.8	35.8	0.2713	-

[a] P-value: Statistical significance at alpha = 0.05

[b] % efficacy = $\frac{\text{Mean no. of lice vehicle-treated group} - \text{Mean no. lice doramectin-treated group}}{\text{Mean no. of lice vehicle-treated group}} \times 100$

Table 2.4 Study 2039B-60-99-120 – Persistent Efficacy (based on Geometric Means) of DECTOMAX Pour-On Against *Linognathus vituli*

Day of Study	Geometric Mean Lice Counts		P-value[a]	% Efficacy[b]
	Vehicle Control	DECTOMAX Pour-On		
-1	122.6	167.7	-	-
35	76.5	0.0	-	100.0
42	50.0	0.0	0.0001	100.0
49	31.3	0.1	0.0001	99.6
56	25.5	0.0	0.0001	100.0
63	19.8	0.1	0.0001	99.7
70	21.0	0.0	0.0001	100.0
77	21.8	0.1	0.0001	99.7
84	14.9	0.1	0.0001	99.2
91	19.6	0.3	0.0001	98.3
98	21.9	0.3	0.0001	98.6
105	15.3	0.4	0.0001	97.4
112	16.2	1.4	0.0001	91.5
119	16.6	2.3	0.0001	86.3
126	15.3	6.6	0.0146	56.6
133	15.3	7.2	0.0269	52.9
140	12.4	7.5	0.1377	39.8
147	10.5	5.7	0.0799	45.9
154	7.0	4.5	0.2335	35.2
161	4.5	7.7	0.1464	-
168	3.1	4.5	0.3595	-
175	2.0	4.6	0.0495	-
182	2.1	4.5	0.0605	-

[a] P-value: Statistical significance at alpha = 0.05

[b] % efficacy = $\frac{\text{Mean no. of lice vehicle-treated group} - \text{Mean no. lice doramectin-treated group}}{\text{Mean no. of lice vehicle-treated group}} \times 100$

4) Adverse Events: No treatment related health problems were observed during this study.

3. TARGET ANIMAL SAFETY

No further target animal safety data were required from the original approval as discussed in the parent NADA 141-095 FOI Summary approval dated September 16, 1997.

4. HUMAN SAFETY

No further human food safety data were required from the original approval as discussed in the parent NADA 141-095 FOI Summary approval dated September 16, 1997. There is a 45-day withdrawal period for slaughter, a withdrawal period for milk has not been established, and a withdrawal period has not been established for pre-ruminating calves.

5. AGENCY CONCLUSIONS

The data submitted in support of this supplemental NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that DECTOMAX Pour-On for cattle when administered once at 500 mcg doramectin/kg body weight is safe and effective for the following persistent effect periods: *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment.

The Agency has concluded that this product may retain over-the-counter marketing status because adequate directions for use have been written for the layperson and the conditions of use prescribed on the label are likely to be followed in practice.

In accordance with 21 CFR 514.106(b)(2)(v), this is a Category II change which did not require a reevaluation of safety or effectiveness data in the parent application. Persistence effectiveness studies were submitted to support extended antiparasitic activity against two ectoparasites.

Under Section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for THREE years of marketing exclusivity beginning on the date of approval. The three years of marketing exclusivity applies only to the additional persistent effect indications for lice listed above.

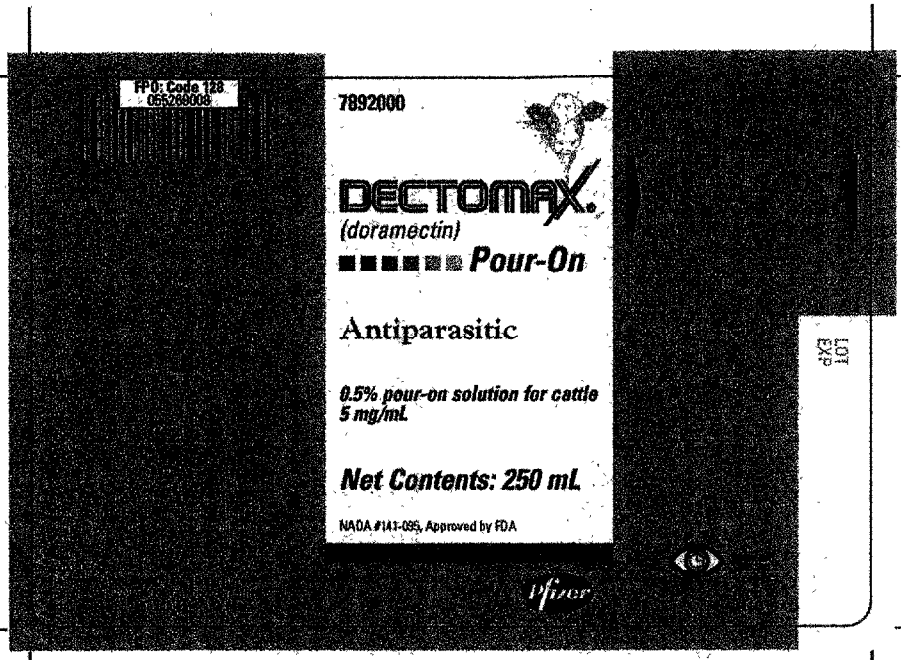
DECTOMAX Pour-On is under the following U.S. patent number:

U.S. Patent Number	Date of Expiration
5,089,480	July 30, 2010

6. ATTACHMENTS

Facsimile Labeling is attached as indicated below:

A. 250 mL, 1 liter, 2.5 liter, and 5 liter – bottle label and box carton
B. Package insert for all container sizes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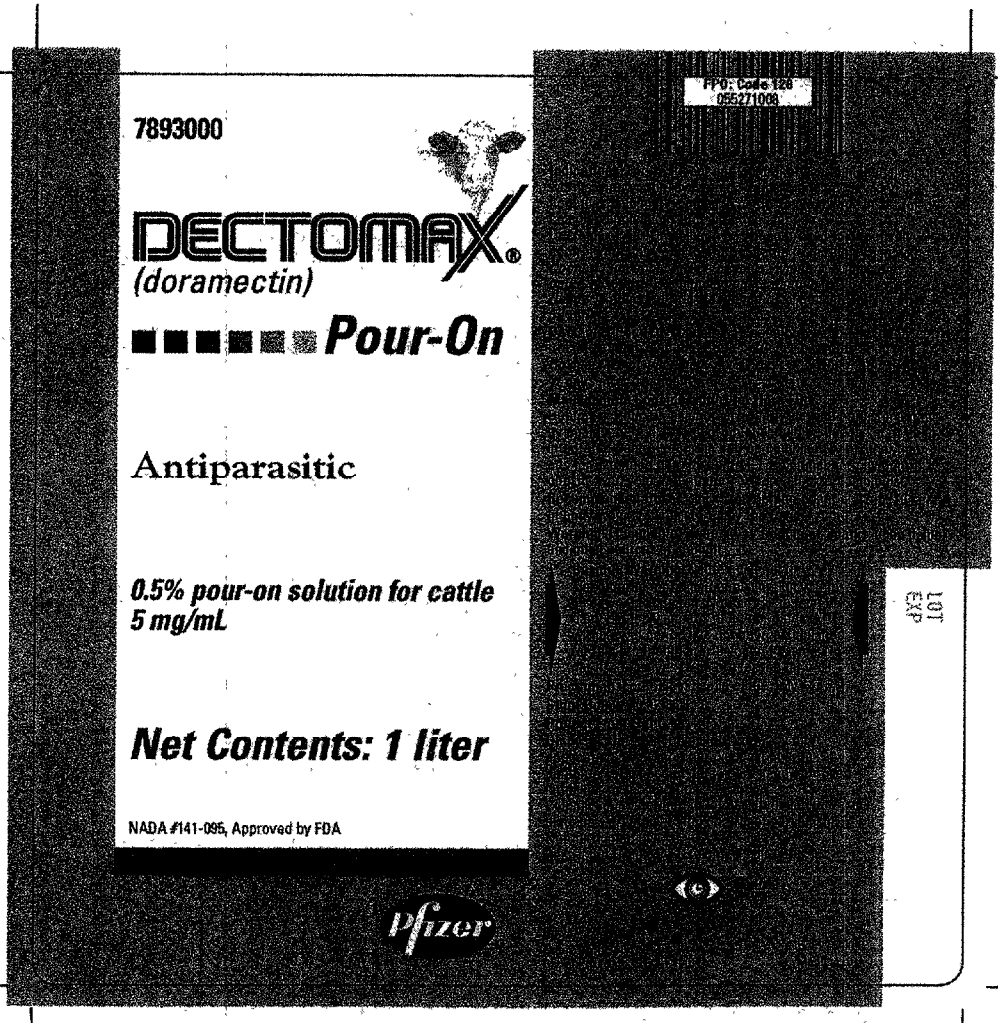
7892000
DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Net Contents: 250 mL
NADA #141-095, Approved by FDA
Pfizer
LOT
EXP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DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Net Contents: 1 liter
NADA #141-095, Approved by FDA
Pfizer
FPO: Code 128
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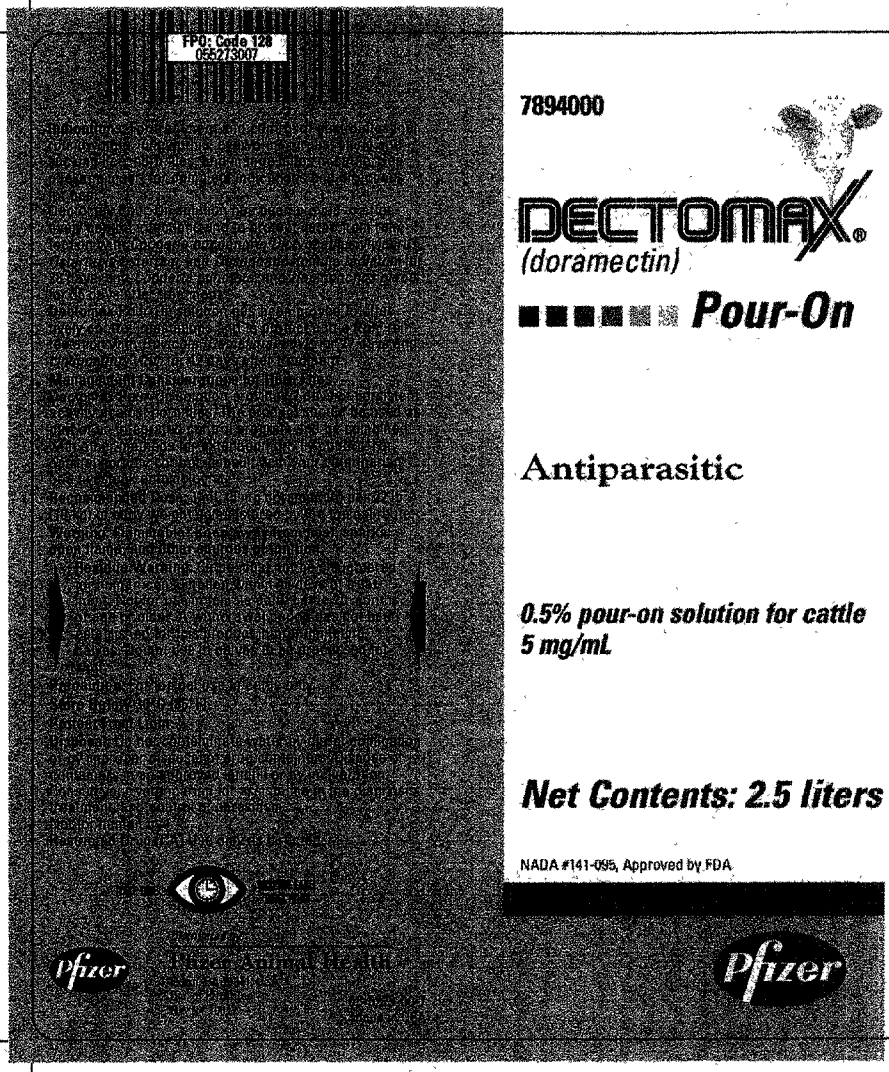
LOT
EXP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7894000
DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Net Contents: 2.5 liters
NADA #141-095, Approved by FDA
Pfizer
Pfizer Animal Health
Pfizer

PP0: Code 128
05527/5007

7895000

DECTOMAX®

(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle
5 mg/mL

LOT
EXP

Net Contents: 5 liters

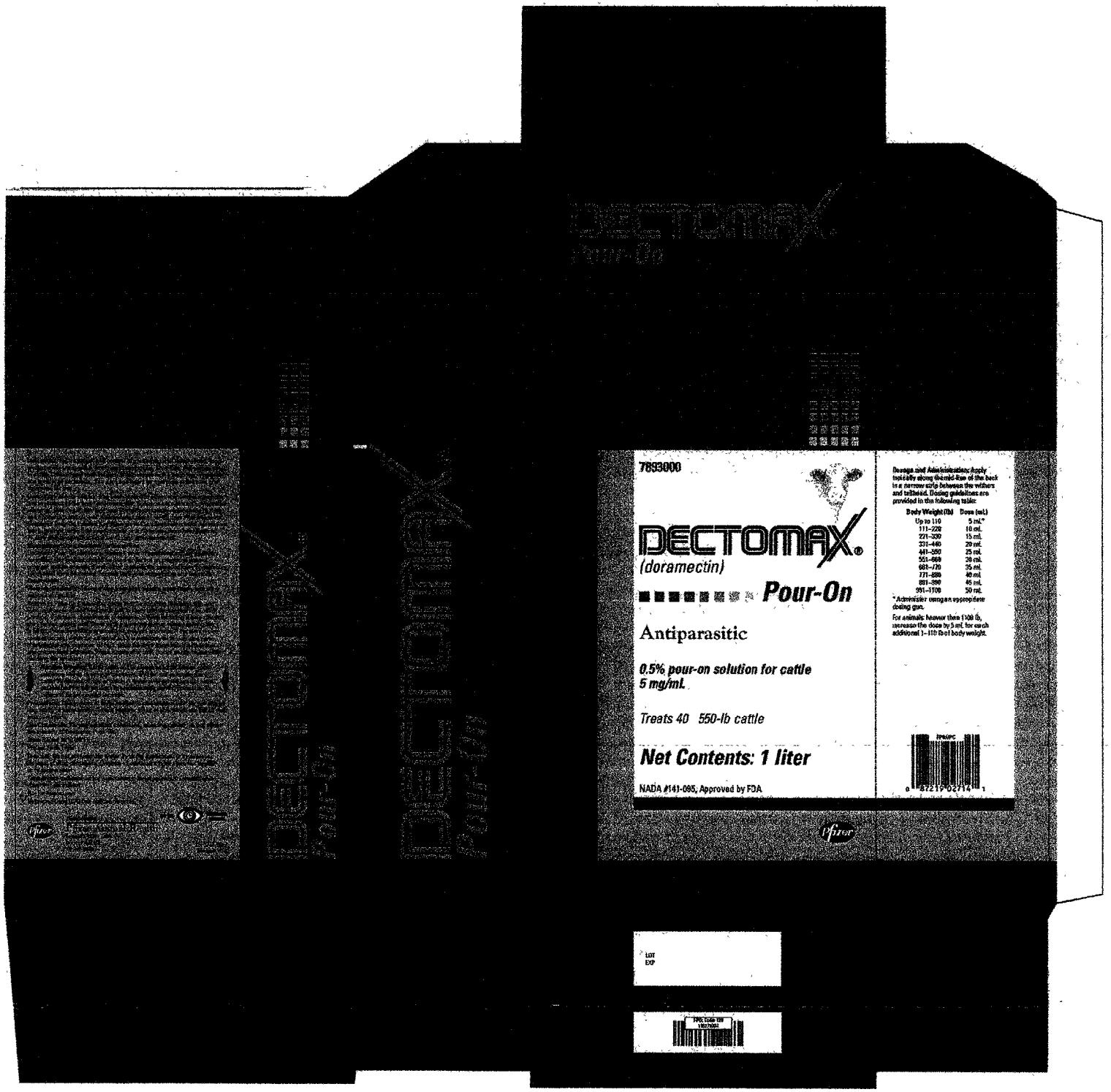
NADA #141-095, Approved by FDA

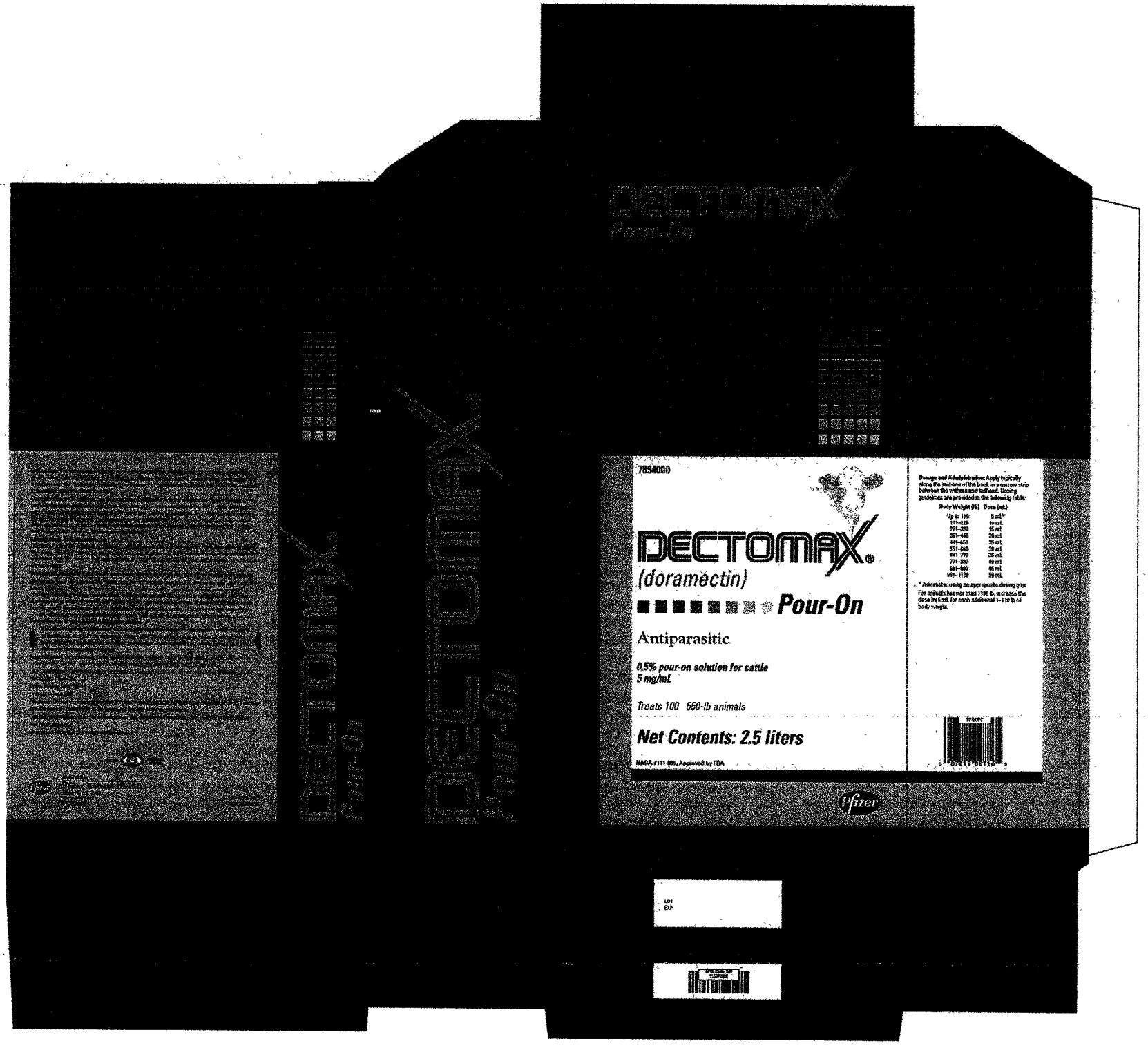
Pfizer

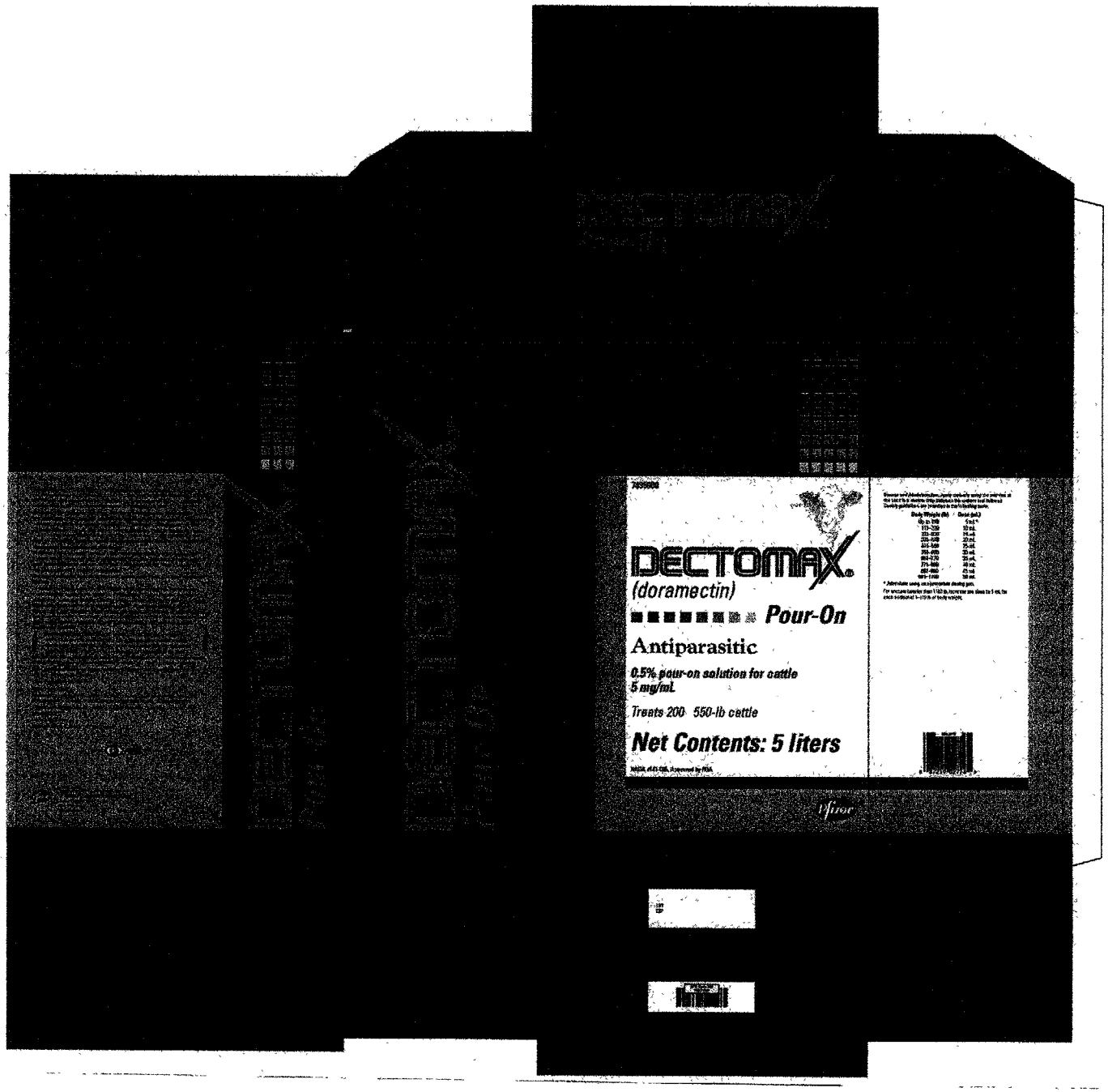
Pfizer Animal Health

Pfizer


7892000
DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Treats 10–550-lb cattle
Net Contents: 250 mL
NADA #141-095, Approved by FDA
Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:
Body Weight (lb) Dose (mL)
Up to 110 5 mL*
111–220 10 mL
221–330 15 mL
331–440 20 mL
441–550 25 mL
551–660 30 mL
661–770 35 mL
771–880 40 mL
881–990 45 mL
991–1100 50 mL
* Administer using an appropriate dosing gun.
For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1–110 lb of body weight.
FPR: 1PC
0 87219 02712 7
Pfizer
Pfizer
LOT
EXP
FPR: Code 120
155268907


DECTOMAX
Pour-On
7893000
DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Treats 40 550-lb cattle
Net Contents: 1 liter
NADA #141-095, Approved by FDA
Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:
Body Weight (lb) Dose (mL)
Up to 110 5 mL*
111–220 10 mL
221–330 15 mL
331–440 20 mL
441–550 25 mL
551–660 30 mL
661–770 35 mL
771–880 40 mL
881–990 45 mL
991–1100 50 mL
* Administer using an appropriate dosing gun.
For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1–110 lb of body weight.
87219-02714 1
Pfizer
LOT
EXP


DECTOMAX
Pour-On
7894000
DECTOMAX®
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Treats 100 550-lb animals
Net Contents: 2.5 liters
NADA #141-305, Approved by FDA
Dosage and Administration: Apply topically along the mid-line of the back in a narrow strip between the withers and tailhead. Dosing guidelines are provided in the following table:
Body Weight (lb) Dose (mL)
Up to 110 5 mL*
111–220 10 mL
221–330 15 mL
331–440 20 mL
441–550 25 mL
551–660 30 mL
661–770 35 mL
771–880 40 mL
881–990 45 mL
991–1100 50 mL
* Administer using an appropriate dosing gun.
For animals heavier than 1100 lb, increase the dose by 5 mL for each additional 1–110 lb of body weight.
Pfizer
LOT
EXP


DECTOMAX
(doramectin)
Pour-On
Antiparasitic
0.5% pour-on solution for cattle
5 mg/mL
Treats 200 550-lb cattle
Net Contents: 5 liters
Pfizer

600692569

FPO: Code 128

DECTOMAX®

(doramectin)

Pour-On

Antiparasitic

0.5% pour-on solution for cattle

5 mg/mL

PRODUCT DESCRIPTION: Dectomax Pour-On solution is a ready-to-use, systemically active, clear, light blue solution containing 0.5% w/v doramectin (5 mg/mL). It is formulated to deliver the recommended dosage of 500 mcg/kg (227 mcg/lb) of body weight when given by topical administration at the rate of 1 mL/22 lb (10 kg) of body weight.

PRODUCT CHARACTERISTICS: Dectomax Pour-On solution is a highly active, broad-spectrum parasiticide for topical administration to cattle. It contains doramectin, a novel fermentation-derived macrocyclic lactone discovered by Pfizer Inc. Doramectin is isolated from fermentations of selected strains derived from the soil organism *Streptomyces avermitilis*.

A primary mode of action of macrocyclic lactones is to modulate chloride ion channel activity in the nervous system of nematodes and arthropods. Macrocyclic lactones bind to receptors that increase membrane permeability to chloride ions. This inhibits the electrical activity of nerve cells in nematodes and muscle cells in arthropods and causes paralysis and death of the parasites. In mammals, the neuronal receptors to which macrocyclic lactones bind are localized within the central nervous system (CNS), a site reached by only negligible concentrations of doramectin.

One dose of Dectomax Pour-On solution effectively treats and controls a wide range of roundworm and arthropod parasites that impair the health and productivity of cattle.

Studies have demonstrated the safety margin of doramectin. In USA trials, no toxic signs were seen in cattle given up to 25 times the recommended dose of Dectomax Injectable solution. A study using Dectomax Injectable solution also demonstrated safety in neonatal calves treated with up to 3 times the recommended dose. In breeding animals (bulls, and cows during folliculogenesis, organogenesis, implantation, and through gestation), a dose 3 times the recommended dose of Dectomax Injectable solution had no effect on breeding performance. A pharmacokinetic study demonstrated that systemic exposure to doramectin from Dectomax Pour-On was less than systemic exposure to doramectin from Dectomax Injectable solution.

PRODUCT INDICATIONS: Dectomax Pour-On solution is indicated for the treatment and control of the following species of gastrointestinal roundworms, lungworms, eyeworms, grubs (see PRECAUTIONS), biting and sucking lice, horn flies, and mange mites in cattle. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Gastrointestinal roundworms
- *Ostertagia ostertagi* (adults and L_4, including inhibited larvae)
- *O. lyrata* (adults)
- *Haemonchus placei* (adults and L_4)
- *Trichostrongylus axei* (adults and L_4)
- *T. colubriformis* (adults and L_4)
- *Cooperia oncophora* (adults[1] and L_4)
- *C. pectinata* (adults)
- *C. punctata* (adults and L_4)
- *C. surnabada* (adults)
- *Bunostomum phlebotomum* (adults)
- *Oesophagostomum radiatum* (adults and L_4)
- *Trichuris* spp. (adults)

[1] Efficacy below 90% was observed against adult *C. oncophora* in some clinical studies.

Lungworms (adults and fourth stage larvae)
- *Dictyocaulus viviparus*

Eyeworms
- *Thelazia gulosa* (adults)
- *T. skrjabini* (adults)

Lice
- Biting Lice
  - *Bovicola (Damalinia) bovis*
- Sucking Lice
  - *Haematopinus eurysternus*
  - *Linognathus vituli*
  - *Solenopotes capillatus*

Grubs
- *Hypoderma bovis*
- *H. lineatum*

Horn Flies
- *Haematobia irritans*

Mange Mites
- *Chorioptes bovis*
- *Sarcoptes scabiei*

Dectomax Pour-On solution has been proved to effectively control infections and to protect cattle from reinfection with *Cooperia oncophora, Dictyocaulus viviparus, Ostertagia ostertagi,* and *Oesophagostomum radiatum* for 28 days; and *Cooperia punctata* and *Haemonchus placei* for 35 days after treatment.

Dectomax Pour-On solution has been proved to effectively control infestations and to protect cattle from reinfestation with *Bovicola (Damalinia) bovis* for 77 days and *Linognathus vituli* for 42 days after treatment.

Management Considerations for Horn Flies

Dectomax Pour-On solution provides 7 days of persistent activity against horn flies. The product should be used as part of an integrated control program and be combined with other methods for extended horn fly control. For optimal horn fly control, consult with your veterinarian or a livestock entomologist.

DOSAGE: Administer Dectomax Pour-On solution to cattle topically at a dosage of 500 mcg doramectin per kg (227 mcg/lb) of body weight. Each mL contains 5 mg of doramectin, sufficient to treat 22 lb (10 kg) of body weight.

For the best results, Dectomax Pour-On solution should be a part of a parasite control program for both internal and external parasites based on the epidemiology of these parasites. Consult a veterinarian or an entomologist for information regarding the most effective timing of applications.

ADMINISTRATION: Dectomax Pour-On solution should be applied topically along the mid-line of the back in a narrow strip between the withers and tailhead.

Dosing Cup (250-mL and 1-L bottles)

A dosing cup is provided for use with Dectomax Pour-On solution supplied in 250-mL and 1-L bottles. The Dectomax Pour-On solution dosing cup should be installed by rotating the cup on the bottle neck until tight. When installed correctly, the spout is aligned at the mid-point on the wide side of the bottle.

The curved end of the dosing cup tube should be positioned at the bottom of the bottle on the side opposite the spout. When the dosing cup is in the closed position ("zero" at set dosage mark on screw), product does not enter the cup reservoir. Select a dose (1 mL per 22 lb (10 kg) of body weight) by twisting the dosing screw on the top of the dosing cup to the desired position. The first complete turn of the dosing screw will set the dose at 10 mL ("10" shows on the screw at set dose mark). Each additional turn increases the dose in 5 mL increments until a maximum dose of 50 mL ("50" is the bottom number showing on screw at the set dose mark) is reached. When body weight is between weight markings on the dosing cup, use the higher dose volume.

To fill the dosing reservoir, hold the bottle upright and squeeze it until a slight excess has been delivered as indicated by the calibration lines. Release the pressure and excess will automatically drain from the reservoir and return to the bottle.

Tilt the bottle to deliver the dose. Dectomax Pour-On solution should be delivered to cattle on the back in a single pass from the withers to the tailhead.

Applicators (2.5-L and 5-L bottles)

Applicators are available for use with Dectomax Pour-On solution supplied in 2.5- and 5-L backpacks. Directions for 2 recommended applicators are provided below. Some applicators may be incompatible with this formulation.

Phillips Pour-on Applicator System

1. Replace the shipping cap on 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring counter clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose to maximum (50 mL). Gently prime the applicator, checking for leaks. To prime, place the nozzle into a clean, dry receptacle and depress lever fully. Pump 3–4 short strokes ensuring that the piston reaches the end of the cylinder, and then release the lever completely to fill the cylinder. A small air bubble may appear within the cylinder. This will not affect the dosing accuracy.
5. Set the required dose and administer.
6. To disconnect the system, proceed as follows:
   a) Set backpack in upward position.
   b) Discharge residual material from the applicator and draw-off tubing into a separate, clean, dry receptacle.
7. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
8. Remove the draw-off cap. Replace with the original cap and tighten firmly.

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Syvret Pour-on Applicator System

1. Replace the shipping cap on the 2.5- or 5-L backpack with the draw-off cap provided and tighten firmly.
2. Thread the draw-off tubing through the anti-kink spring. Attach the tube to the draw-off cap. Screw the spring clockwise over the tubing and draw-off spigot.
3. Invert the backpack.
4. Set the dose at the maximum (50 mL) by unscrewing the adjuster at the base of the handle. Gently prime the applicator, checking for leaks. To prime, point the nozzle into a clean, dry receptacle and gently pump the lever back and forth to expel air from the system. When the barrel completely fills after every priming stroke, set the dose.
5. Set the dose as follows:
   a) Use the handle to align the middle of the blue plunger ring with the chosen mark on the barrel. Tighten the adjuster screw against the handle.
   b) Secure the dose with the adjuster screw locknut.

Note: Dose accuracy can be checked by dispensing a known number of set doses into a measuring cylinder. Correct any inaccuracy by adjusting the dose setting screw. Repeat this procedure until desired accuracy is achieved.

6. Administer each dose by fully depressing the handle so that the plunger travels its entire set length. Release the handle and the applicator will automatically refill.
7. To disconnect the system proceed as follows:
   a) Set backpack in upward position.
   b) Discharge residual material from the applicator and draw off tubing into a separate, dry receptacle.
8. Follow the manufacturer's recommendation for care and maintenance of the dosing applicator.
9. Remove the draw-off cap. Replace with the original cap and tighten firmly.

WARNING: Flammable! Keep away from heat, sparks, open flame, and other sources of ignition. Not for human use. Keep out of reach of children. The Material Safety Data Sheet (MSDS) contains more detailed occupational safety information. To report adverse effects in users, to obtain more information, or to obtain an MSDS, call 1-800-366-5288.

Dectomax Pour-On solution for cattle may be irritating to human skin and eyes, and users should be careful not to apply it to themselves or to other persons. Operators should wear protective clothing including a long-sleeved shirt, rubber gloves, and boots with a waterproof coat when applying the product. Protective clothing should be washed after use. If accidental skin contact occurs, wash the affected area immediately with soap and water. If accidental eye exposure occurs, flush the eyes immediately with water and get medical attention.

RESIDUE WARNING: Cattle must not be slaughtered for human consumption within 45 days of treatment. Not for use in female dairy cattle 20 months of age or older. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

PRECAUTIONS:

Dectomax Pour-On solution has been developed specifically for use in cattle only. This product should not be used in other animal species as severe adverse reactions, including fatalities in dogs, may result.

This product is to be applied to skin surface only. Do not administer orally or parenterally.

Do not apply to areas of skin which are caked with mud or manure.

Wash hands after use.

Do not smoke or eat while handling the product.

Cloudiness in the formulation may occur when Dectomax Pour-On solution is stored at temperatures below 0°C (32°F). Allowing to warm to room temperature will restore the normal appearance without affecting efficacy.

Dectomax Pour-On solution is highly effective against cattle grubs. However, proper timing of treatment is important. For most effective results, cattle should be treated as soon as possible after the end of the heel fly (warble) season.

Destruction of *Hypoderma* larvae (cattle grubs) at the period when these grubs are in vital areas may cause undesirable host-parasite reactions including the possibility of fatalities. Killing *H. lineatum* when it is in the tissue surrounding the gullet may cause bloat; killing *H. bovis* when it is in the vertebral canal may cause staggering or paralysis. These reactions are not specific to treatment with Dectomax Pour-On solution, but can occur with any successful treatment of grubs. Cattle should be treated either before or after the migratory phase of grub development. Consult your veterinarian concerning the proper time for treatment.

Cattle treated with Dectomax Pour-On solution after the end of heel fly season may be re-treated with Dectomax Pour-On during the winter for internal parasites, mange mites, or biting and sucking lice, without danger of grub-related reactions. A planned parasite control program is recommended.

USE CONDITIONS: Varying weather conditions, including rainfall, do not affect the efficacy of Dectomax Pour-On.

ENVIRONMENTAL SAFETY: Studies indicate that when doramectin comes in contact with the soil, it readily and tightly binds to the soil and becomes inactive over time. Free doramectin may adversely affect fish and certain aquatic organisms. Do not permit cattle to enter lakes, streams or ponds for at least 6 hours after treatment. Do not contaminate water by direct application or by the improper disposal of drug containers. Dispose of containers in an approved landfill or by incineration. As with other avermectins, doramectin is excreted in the dung of treated animals and can inhibit the reproduction and growth of pest and beneficial insects that use dung as a source of food and for reproduction. The magnitude and duration of such effects are species and life-cycle specific. When used according to label directions, the product is not expected to have an adverse impact on populations of dung-dependent insects.

Store Below 30°C (86°F)

Protect From Light

HOW SUPPLIED: Dectomax Pour-On solution is available in 250-mL, 1-L, 2.5-L, and 5-L multi-dose containers.

NADA #141-095, Approved by FDA

Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

Not for human use.

Restricted Drug (CA) Use only as directed.

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Pfizer Animal Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

TAKE TIME  OBSERVE LABEL DIRECTIONS

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